REMARKS

Claims 35-46 and 48 are pending. Claims 1-34, 47, and 49-60 are cancelled without prejudice. Claims 35 and 48 are currently amended.

Reconsideration of the application is requested.

Claim 35 has been amended to incorporate the markush group of compound classes from claim 47, and to limit the compounds to TLR 7 and/or 8 agonists. Claim 48 has been amended to change dependency to claim 35.

§ 112 Rejections

Claims 35-51 stand rejected under 35 USC § 112, first paragraph, as allegedly failing to comply with the written description requirement.

Amended claim 35 is limited to a markush group of compound classes for which there have been a large number of compounds shown to be TLR 7, 8, and 7/8 agonists. Publications disclosing various such compounds and activity are found on, e.g., pages 17 and 18 of the application.

Accordingly, it is submitted that the rejection under 35 USC 112, first paragraph, should be withdrawn.

Claims 35-51 stand rejected under 35 USC 112, second paragraph, as allegedly being indefinite due to the use of acronyms. Claim 35 has been amended to spell out the first instances of "immune response modifier (IRM)". It is believed that this is deemed sufficient under current PTO practice and, accordingly, the rejection has been overcome. Applicants will if requested spell out the term IRM in the other claims as well.

§ 103 Rejections

Claims 35-51 stand rejected under 35 USC § 103(a) as being unpatentable over Tomai (US 20030133913) in view of Allen (US 6334856) and Babiuk (Journal of Controlled Release, 66, 2000). Applicants respectfully traverse.

Claim 35 is independent and claims 36-46 and 48 all depend therefrom.

The Office Action notes that Tomai discloses a method of inducing antigen presentation by dendritic cells **in vitro**. Allen discloses microneedle devices for drug delivery, including vaccines, but does not disclose their use in conjunction with the vaccine adjuvant compounds of the present claims. Babiuk discloses cutaneous vaccination to dendritic cells. The Office Action does not, however, point to any actual disclosure in Tomai, Allen, or Babiuk teaching the delivery of the claimed IRM compounds in vivo to a biological barrier such as the skin or mucosa, nor does the Office Action identify a rationale under which the ordinarily skilled artisan would have found it obvious to deliver the claimed IRM compounds *in vivo* to a biological barrier. Rather, the Office Action appears to follow a rationale allegedly supporting delivery of antigens to a biological barrier, but not supporting delivery of the claimed IRM compounds. The Office Action follows the reasoning that Tomai teaches *in vitro* stimulation of dendritic cells by exposing the cells to **antigen** (i.e. vaccine) and then contacting the cells with IRM compounds, Allen teaches "microneedle devices…to deliver vaccines", and Babiuk "teaches the skin may be one of the best sites for **vaccination**" because "immune competent dendritic cells are found" throughout the epidermis and "dendritic cells induce immunity to the foreign **antigens** they encounter in the skin" (See 9/15/10 Office Action, pg 7, emphasis added). Indeed it is not apparent how the alleged predictability of success for IRM compounds delivered across a biological barrier, as required by Applicants' claims, flows from the Examiner's conclusion that success may be predicted for the delivery of the antigens: "Babiuk provides a showing and express suggestion that the method of contacting a biological barrier as…taught in Allen could be used to deliver **vaccines** to dendritic cells and stimulate specific responses to **antigens**" and therefore suggests an improvement to the **in vitro** methods of Tomai (See 9/15/10 Office Action, pg 8, emphasis added). The Office Action instead fails to show how one of ordinary skill would be motivated to deliver the claimed IRM across a biological barrier or predict success for such delivery of the claimed IRM compounds. Neither Babiuk nor Allen teach delivery of the claimed IRM compounds by contacting a biological barrier—thus neither remedy the deficiency of Tomai acknowledged by the examiner, "Tomai does not teach the step of contacting a biological barrier" (See 9/15/10 Office Action, page 8). There is also no indication that the IRM compounds would be successful delivered in this fashion. Thus the Office Action fails to present a *prima facie* case for obviousness.

Applicants direct the Examiner's attention to Cormier (US 2002/0193729, not cited by examiner), which does list IRM compounds imiquimod and resiquimod for possible use in connection with a microneedle device. However, Cormier discloses imiquimod and resiquimod in a laundry list of compounds for possible delivery in combination with a vaccine in a microneedle coating or reservoir. There are no examples using imiquimod or resiquimod in Cormier, nor is there any apparent recognition of the substantial benefits possible by delivering these and other IRM compounds using microneedles, nor is there any apparent recognition that the IRM compounds do not need to be coated on the microneedles with a vaccine. Thus Cormier does not recognize the claimed features of Applicants' invention.

At the time of the invention there was no way to predict how the claimed TLR 7 and/or IRM compounds would behave when delivered via microneedles, for example whether they would disperse systemically too quickly to be effective. Accordingly, it is submitted that the claims would not have been obvious.

In view of the above, it is submitted that the application is in condition for allowance.

Examination and reconsideration of the application as amended is requested.

Applicant requests a telephone interview to more fully understand the examiners position and advance this case to issuance.

Respectfully submitted,

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